

Remarks

Amendments to the Claims

The amendments to the claims do not add new matter and are addressed in connection with the rejections under 35 U.S.C. § 112 ¶ 2 and § 102(e), below.

Objections to the Specification and Amendments

The Office Action makes various objections to the specification, requesting that trademarks be indicated. The specification is amended to identify trademarks.

The Office Action also requested that the amino acid sequences LPXTG and GSGGGG be identified with sequence identifiers. A substitute sequence listing accompanies this paper. The substitute sequence listing is identical to the sequence listing filed October 22, 2007 except that it now includes SEQ ID NOS:92 (GSGGGG) and SEQ ID NO:93 (LPXTG). The specification is amended to incorporate the substitute sequence listing by reference and to insert the new sequence identifiers.

Rejection Under 35 U.S.C. § 101

Claims 1, 14, and 17 are rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter. Claim 1 is amended to recite that isolated GBS antigens. Claim 14 is amended to recite an isolated fusion protein, which also addresses the rejection of claim 17. Please withdraw the rejection.

Rejections Under 35 U.S.C. § 112 ¶ 2

The Office Action rejects claims 1-4, 8-10, 14-17, and 27-30 as indefinite under 35 U.S.C. § 112 ¶ 2. Claims 2, 15, 27, and 30 are canceled, which moots points (c), (f), (g), (h), and (j). Applicants' response to the remaining points set forth on pages 5 and 6 of the Office Action follow.

- (a) Independent claim 1 is amended as the Office Action suggests to recite "Group B streptococcus (GBS)."
- (b) Claims 1, 14, 16, and 17 are amended to delete the phrase "as represented by."
- (d) Claim 1 is amended to recite fragments of GBS 80 and GBS 322 which comprise an immunogenic epitope. The specification supports this amendment, for example, on page 3, lines 11-18 and on page 5, lines 13-18. Particular fragments of GBS 80 are disclosed on pages 5-7 and in Tables 1 and 2 on page 8. Particular fragments of GBS 322 are disclosed on pages 28-29.
- (e) Claim 14 is amended to recite a fragment rather than a portion. Fragments are addressed above.
- (i) Claim 8 is amended as the Office Action suggests to recite "the GBS 80."
- (k) Claim 16 is amended as the Office Action suggests to recite "said at least one different GBS antigen."
- (l) Claim 17 is amended to provide antecedent basis for the recited GBS 80 and GBS 322 antigens.
- (m) Claim 28 is amended to delete the phrase "surface immunogenic protein (sip)" and recite instead a second isolated GBS antigen which comprises the amino acid sequence SEQ ID NO:38. The specification supports this amendment on page 28,

line 12 to page 29, line 14, where “surface immunogenic protein” is identified as GBS 322, which comprises SEQ ID NO:38.

- (n) Claim 29 is amended to recite the phrase “amino acid sequence shown in SEQ ID NO:”
- (o) The amendments to independent claims 1, 14, and 28 address the rejections of their dependent claims.

The amended claims are definite. Please withdraw the rejections.

Rejection Under 35 U.S.C. § 102(e)

Claims 1-4, 8-10, 14-17, and 27-30 are rejected under 35 U.S.C. § 102(e) as anticipated by Tettelin (WO 2004/018646). Claims 2, 15, 27, and 30 are canceled. Applicants respectfully traverse the rejection of the remaining claims.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Tettelin does not meet this standard.

Independent claim 1 is directed to a composition comprising two isolated GBS antigens: (1) a GBS 80 antigen or a fragment thereof, wherein the GBS 80 antigen comprises an amino acid sequence selected from the group consisting of SEQ ID NOS:2, 3, 4, 6, 7, 8, and 9; and (2) a GBS 322 antigen or a fragment thereof, wherein the GBS 322 antigen comprises the amino acid sequence SEQ ID NO:38. Tettelin does not disclose this composition and does not anticipate claim 1 or its dependent claims.

Independent claim 14 is directed to a fusion protein comprising (1) a fragment of a GBS 80 antigen, wherein the GBS 80 antigen comprises an amino acid sequence selected from the group consisting of SEQ ID NOS:2, 3, 4, 6, 7, 8, and 9; and (2) a fragment of at least one different GBS antigen selected from a group of recited GBS antigens. Tettelin does not disclose a fusion protein comprising the recited elements and therefore does not anticipate claim 14 or its dependent claims.

Please withdraw the rejection.

Objection to the Claims

The Office Action objects to claims 1, 8, 10, 14-17, and 27-30 “for not leaving a space after the limitation ‘SEQ ID NO:.’” Office Action at page 12. Claims 15, 27, and 30 are canceled. The remaining claims are in proper form. The sequence listing rules are set forth in 37 C.F.R. §§ 1.821–1.825 and discussed in M.P.E.P. §§ 2420–2435. There is no requirement in either authority for a space after “SEQ ID NO:.” In fact, in each example given, there is no space after “SEQ ID NO:.” For example:

- 37 C.F.R. § 1.821(b) (the table, indicating “SEQ ID NO:#” as the entry for <210>);
- 37 C.F.R. § 1.821(d) (“ . . . preceded by ‘SEQ ID NO:’ in the text . . .”);
- M.P.E.P. § 2422.02 (“ . . . and the sequence identifier (‘SEQ ID NO:X’) must be used . . .” and “ . . . the sequences may be described as SEQ ID NO:X . . .”); and
- M.P.E.P. § 2422.03 (“ . . . language such as ‘residues 14 to 243 of SEQ ID NO:23’ is permissible . . .” and “The use of sequence identification numbers (SEQ ID NO:X) only provides a shorthand . . .”).

The claims as written are proper. Please withdraw the objection.

Respectfully submitted,

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